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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/773,380 | 02/06/2004 | Yu Wang | 019934-003800US | 6355 |

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

| EXAMINER | |
|---|---|
| GAMETT, DANIEL C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/773,380 | WANG ET AL. | |
| | Examiner | Art Unit | |
| | Daniel C. Gamett, PhD | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/4/04 01/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's election without traverse of claims 1-9 in the reply filed on 06/20/2006 is acknowledged.

2. Claims 10-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/20/2006.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO/2001/027146, published April 19,2001 (Cite No. AB on IDS). Claim 9 is drawn to method for screening for a modulator of an activity of CCX chemokine receptor (CCX CKR), comprising: (a) contacting a cell comprising a recombinant construct encoding CCX CKR with a test agent in the absence of a ligand that specifically binds CCX CKR; and (b) determining the effect of the test agent on the CCX CKR activity. WO/2001/027146 discloses the CCX CKR polypeptide, the encoding polynucleotide, and assay methods which are capable of screening compounds that modulate the activity of the CCX CKR both in the presence and absence of

known CCX CKR ligands (see pp. 33-38). These teachings are embodied in Claim 29, which recites, "A method of identifying a modulator of CCX CKR activity comprising contacting a cell expressing a recombinant polypeptide of claim 1 and a test compound and assaying for a biological effect that occurs in the presence but not absence of the test compound, wherein a test compound that induces a biological effect is identified as a modulator of CCX CKR activity." WO/2001/027146 further teaches that a variety of assays can be used to evaluate the CCX CKR modulators, including CCX CKR binding assays, CCX CKR signaling assays, chemotaxis assays, second messenger levels, i. e., $Ca^{++}$; cell proliferation; inositol phosphate pool changes; and other assays of cellular response (p. 34, lines 13-16). Thus, WO/2001/027146 fully anticipates the generic method of instant claim 9 and the measurement of cell proliferation (claims 1 and 2). The use of an antibody to modulate CCX CKR activity (as in claim 8) is taught in WO/2001/027146 at least at page 29, line 30.

5. Claims 1, 2, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US2002061522 (Glucksmann *et al*), 23 May 2002 (Cite no. AA on IDS). The protein designated "2398" (SEQ ID NO:8) in Glucksmann *et al.* is identical to CCX CKR. Claims 20-22 and paragraphs [0043], [0046-0048], and [0382-0387] recite and teach methods of identifying agents, including antibodies, that modulate the activity of 2398. Determining the ability of the test compound to modulate 2398 activity can be accomplished by monitoring, for example, cell signaling, cell growth, or cell differentiation [0387]. Therefore the teachings of Glucksmann *et al.* fully anticipate the methods recited in instant claims 1,2,8, and 9.

6. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by US 20010016336, August 23, 2001 (Ellis; IDS cite no. A5). The protein designated "HFIAO41" (SEQ ID NO:2)

in Ellis is identical to CCX CKR. Ellis teaches the use of cells expressing HFIAO41 to screen for compounds capable of stimulation or inhibition of a response at [0080-0087] thereby anticipating claim 9.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO/2001/027146, published April 19,2001. As noted above, WO/2001/027146 teaches that a variety of assays can be used to evaluate the CCX CKR modulators, including CCX CKR binding assays, CCX CKR signaling assays, chemotaxis assays, second messenger levels, i.e., $Ca^{++}$; cell proliferation; inositol phosphate pool changes; and other assays of cellular response (p. 34, lines 13-16), thus fully anticipating independent claim 1 of the instant application. Various endpoints related to cell proliferation, such as cell counts (claim 3), DNA replication (claim 5), or expression of cell cycle antigens (claim 6) would be obvious to one of skill in the art, as would the use of appropriate controls (claim 7) and the measurement of metabolic activity (claim 4).

9. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2002061522 (Glucksmann *et al*), 23 May 2002. As noted above, the teachings of Glucksmann *et al.* fully anticipate the methods recited in instant claims 1 and 2. Various

endpoints related to cell proliferation, such as cell counts (claim 3), DNA replication (claim 5), or expression of cell cycle antigens (claim 6) would be obvious to one of skill in the art, as would the use of appropriate controls (claim 7) and the measurement of metabolic activity (claim 4).

***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6835547 ('547). Although the conflicting claims are not identical, they are not patentably distinct from each other because one of skill in the art would recognize each of the claimed methods as being an obvious modification the other. Instant Claim 9 is drawn to method for screening for a modulator of an activity of CCX chemokine receptor (CCX CKR), comprising: (a) contacting a cell comprising a

recombinant construct encoding CCX CKR with a test agent in the absence of a ligand that specifically binds CCX CKR; and (b) determining the effect of the test agent on the CCX CKR activity. Claim 1 of the '547 patent ('547-1), recites a similar method, except that contacting with a test compound is to be done in the presence of a chemokine that binds CCX CKR; several chemokines are recited. One of skill in the art would recognize that, while both methods identify modulators of CCX CKR activity, the two methods are intended to infer different mechanisms of action of the modulator. That is, the instantly claimed method would identify a new agonist or an inhibitor of basal receptor activity, whereas the modulator identified in '547-1 might act by altering receptor-ligand interactions. An investigator interested in mechanisms would logically perform the instantly claimed method on any test compound that scored positive in the method of '547-1. The '547 patent clearly suggests performing the method either in the presence or absence of a chemokine at column 3, lines 21-33; this suggestion is made in the context of determining the mode by which compounds interact with CCX CKR (see paragraph bridging columns 2-3).

12. The '547 patent teaches that a variety of assays can be used to evaluate the CCX CKR modulators, including CCX CKR binding assays, CCX CKR signaling assays, chemotaxis assays, second messenger levels, i. e., $Ca^{++}$; cell proliferation; inositol phosphate pool changes; and other assays of cellular response (column 25, lines 38-43). This teaching is embodied in dependent claims '547-2 and '547-3, which add limitations as to the biological activity that indicates CCX CKR activity. Among these is "cell proliferation", which is the recited in instant claims 1 and 2. Various endpoints related to cell proliferation, such as cell counts (claim 3), DNA replication (claim 5), or expression of cell cycle antigens (claim 6) would be obvious to one of skill in the art, as would the use of appropriate controls (claim 7) and the measurement of

metabolic activity (claim 4). The use of an antibody to modulate CCX CKR activity (as in claim 8) is taught in the '547 pate at least at column 22, lines 16 and 17.

13. Thus, each limitation in the instant claims that is not also found in claims 1-3 of the '547 patent is either obvious to one of skill in the art, specifically suggested in the '547 patent, or both. Therefore this instant claims and claims 1-3 of the '547 patent do not recite patentably distinct inventions.

14. Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 11170216. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 9 is a species that would anticipate the generic method of claim 11170216-29. Instant claim 9 is drawn to method for screening for a modulator of an activity of CCX chemokine receptor (CCX CKR), comprising: (a) contacting a cell comprising a recombinant construct encoding CCX CKR with a test agent in the absence of a ligand that specifically binds CCX CKR; and (b) determining the effect of the test agent on the CCX CKR activity. Claim 11170216-29 is drawn to a method of identifying a modulator of CCX CKR activity comprising contacting a cell expressing a recombinant polypeptide of claim 1 and a test compound and assaying for a biological effect that occurs in the presence but not absence of the test compound, wherein a test compound that induces a biological effect is identified as a modulator of CCX CKR activity. Therefore, the difference between the claims lies in the instant recitation of "absence of a ligand that specifically binds CCX CKR". Thus, the instant method is a species of the generic method of claim 29. Further, the specific method of claim 9 is an obvious

modification of the method of claim 29 for reasons that are analogous to the relationship of instant claim 9 and claim '547-1 described above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## *Conclusion*

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO9933876, Cite No. B3: the provided abstract indicates that a methods related to the instant claims are contemplated in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D.,whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
1 August 2006

DAVID S. ROMEO
PRIMARY EXAMINER